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| EXAMINER | |
|---|---|
| HUMPHREY, LOUISE WANG ZHIYING | |
| ART UNIT | PAPER NUMBER |
| 1648 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/519,114 | ALLNUTT ET AL. | |
| | Examiner | Art Unit | |
| | LOUISE HUMPHREY | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *27,30-32,34,35 and 42-46* is/are pending in the application.

4a) Of the above claim(s) *42-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27,30-32,34 and 35* is/are rejected.

7)☒ Claim(s) *27 and 30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

This Office Action is in response to the amendment filed 4 November 2010.

The examiner of your application in the Patent and Trademark Office has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Louise Humphrey, Art Unit 1648.

Claims 1-26, 28, 29, 33, 36-41, 47 and 48 have been cancelled.

Claims 27, 30-32, 34, 35 and 42-46 are pending.

Claims 42-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

Claims 27, 30-32, 34 and 35 are currently examined.

## WITHDRAWN OBJECTIONS/REJECTIONS

The objection of claims 31 and 34 is withdrawn in view of Applicant's amendment.

The rejection of claims 27, 30-32, 34, 35 and 37 under 35 U.S.C. §112, second paragraph, as being indefinite is withdrawn in view of the Applicants' amendment.

The rejection of claims 27, 30, 31 and 34 under 35 U.S.C. §102(e) as being anticipated by Bachmann *et al.* (US 2003/0099668 A1) is withdrawn in view of the Applicant's amendment.

### *Claim Objections*

Claim 27 and 30 are objected to because of the following informalities:

In claim 27, the phrase “producing a construct comprising a recombinant virus-like particle” in the preamble does not agree with the last method step (f), which yields the end result of expression of the recombinant virus-like particle. Thus, it appears that the phrase "a construct comprising" following the recitation of word "producing" should be deleted.

In claim 30, the word “sequence” should be in plural form.

Appropriate correction is required.

### *Response to Arguments*

Applicant's arguments with respect to claims 27, 30, 31 and 34 have been considered but are moot in view of the **new ground of rejection necessitated by amendment**.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27, 30-32, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bachmann *et al.* (US 2003/0099668 A1; of record as cited in previous Office Action) in view of Russell-Jones (2000).

The instant claims 27, 30 and 31 are directed to a method comprising: isolating a viral coat capsid protein sequence from a viral genome that infects a host organism of yeast, bacteria, algae, fish or crustacean; inserting into the viral capsid protein sequence at least one first exogenous sequence encoding an antigen or allergen and at least one second exogenous sequence encoding a tissue-targeting protein with binding affinity for a receptor on a stomach or intestinal cell wall tissue of the target animal; cloning the viral coat protein sequences comprising the first and second exogenous sequences into an appropriate vector; and transforming the host organism with the vector for expression of a recombinant virus-like particle (VLP) and the exogenous peptides or proteins therein, wherein the host organism is not the target animal. Dependent claim 30 further requires two first exogenous sequences to be inserted whereas claim 31 recites the function of the one or more second exogenous sequences to target the expressed recombinant VLP to a specific location on intestinal cell wall of the target animal. Dependent claims 32 and 35 further require isolating more than one viral coat protein sequences.

The instant claim 34 is directed to a genetic construct comprising at least one viral coat protein coding sequence that can be expressed in a host organism of yeast, bacteria, algae, fish or crustacean, and a first and second exogenous sequence encoding an antigenic or allergenic protein and a stomach- or intestinal cell wall-targeting protein, which are displayed on the surface of the expressed viral coat protein, and wherein the host organism is not the target animal.

Bachman et al. discloses a method of producing recombinant VLP comprising preparing the fusion protein construct by inserting the epitope sequence of at least one antigen or antigenic determinant within the A1 coat protein of bacteriophage Qβ for expression in bacteria (page 22, [0251]-[0253]), or comprising fusion of at least one antigen or antigenic determinant by internal insertion into the p1 capsid protein of Ty sequence and making vectors for expression of fusion proteins in yeast (page 22, [0257]-[0258]). Bachman et al. specifically discloses methods comprising antigens (indicating more than one sequence as required by claim 30) fused to the VLP by insertion within the sequence of the VLP building monomers. See page 23, para. [0261]. Bachman et al. also discloses that the antigen is a DNA, protein, polypeptide or peptide, lipid, carbohydrate, or an inorganic molecule, which include allergens, autoantigens and antigens from pathogens or tumors. See page 27-31, especially para. [0303]-[0305].

Bachman et al. further discloses chimeric DNA containing a sequence coding for VLP and a sequence coding for the antigen/immunogen, which can be expressed in yeast or in bacteria. See page 23, para. [0266]. This chimeric DNA meets the limitation of a genetic construct in the instant claim 34.

Bachman et al. does not explicitly disclose inserting a second exogenous stomach/intestine-targeting protein sequence into the viral coat protein. Bachman et al., however, suggests attaching, enclosing or fusing immunostimulatory substances to the VLP in addition to the antigen bound to the VLP (page 3, para. [0029]).

Russell-Jones explicitly suggests conjugating or covalently linking antigens to carrier proteins which can bind in a lectin-like fashion to the intestinal epithelial cells for oral vaccine delivery. See page 51, right column.

With respect to claims 27, 30, 31 and 34, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the genetic construct or the method of Bachman et al. by additionally inserting into the viral capsid protein a second exogenous protein that targets the stomach or the intestinal cell wall as suggested by Russell-Jones. One having ordinary skill in the art would have been motivated to make such a modification to more effectively elicit mucosal immune response as disclosed by Russell-Jones. There would have been a reasonable expectation of success, given the results of several immunogenic studies summarized by Russell-Jones.

With respect to claims 32 and 35, it would have been obvious to one of ordinary skill in the art at the time the invention was made to isolate more than one viral coat protein sequence, each of which is taught by the prior art as disclosed by Bachman et al. to be useful for the same purpose of displaying exogenous protein or peptide on the surface of the recombinant VLP. See MPEP 2144.06 [R-6] Art Recognized Equivalence for the Same Purpose >I.< COMBINING EQUIVALENTS KNOWN FOR THE SAME PURPOSE. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re*

*Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.).

Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

## ***Conclusion***

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

## ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas, can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. H./
Examiner, Art Unit 1648

/Zachariah Lucas/
Supervisory Patent Examiner, Art Unit 1648